UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,891	02/01/2005	Sergio Restelli	2504-1159	6662

466 7590 11/16/2006

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,891	RESTELLI ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 1/17/2006.

2. The reply filed on 7/21/2006 as a petitions to withdraw the holding of abandonment has been dismissed as moot because the record fails to disclose that an abandonment has occurred in this application and that the response filed on 1/17/2006 appears to have been appropriately handled in accordance to MPEP 508.03, as it is present in the file.

3. The Examiner notes that this application had docketing issues that resulted in the amendment filed on 1/17/2006 to not be considered in a timely manner; however, at no time was the case abandoned. The issues have been resolved and the case has now been docketed to the current Examiner for continuation of prosecution.

4. In the reply filed on 1/17/2006, the Applicant amended claims 1 and 9; added new claims 11 and 12; and amended the specification without entering new matter

5. Thus, claims 1-12 are pending.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 2/1/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

7. The claims are objected to because they include reference characters which are not enclosed within parentheses.

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

See claims 11 and 12, lns 8 and 5 respectively.

8. Claim 4 is objected to because of the following informalities: Claim 4, ln 2 recited "the tat". Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recited the limitation "relative to the needle body" on ln 22. The Examiner notes that the body (30) of the guide needle appears to be the needle body (30) and thus the body (30) cannot be locked relative to the needle body because they are the same element. The Examiner assumes the Applicant intended to recite the catheter body (10).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 2, 5, 6, 9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohammad MBBS (6379337). Mohammad MBBS discloses a safety catheter comprising: a catheter body (26) having an axial channel communicating with a sheath or cannula (15) for administration of fluids, a guide needle (1), insertable through the channel of the catheter body, into the sheath to guide it during insertion into the patient's body, and a guide needle body supporting said guide needle insertable inside the catheter body and provided with at least one seat (Fig 9, wherein a medical instrument can be considered to be a blood collection chamber) for coupling with medical instruments, characterized in that said body of the guide needle is mounted slidably inside the catheter body to be able to slide from a forward working position wherein the guide needle protrudes forward from the catheter body (Fig 13a, b; col 5, lns 12-col 8, lns 14) to a retracted safety position wherein the entire guide needle is protected inside the catheter body (Figs 13a, b; col 5, lns 12-col 8, lns 14), there being provided locking means (7, 8, 27b), disposed in said body of the guide needle, cooperating with complementary locking or stop means (20d, 20c) disposed in the catheter body, to lock the body of the guide needle respectively in said forward working position and in said retracted safety position, and the needle moving into the retracted safety position in a continuous movement under a pushing force of a spring means

(100); including a safety catheter in that said locking means comprises a pin and said complementary locking means provided in the catheter comprises two seats disposed at the front and at the rear to receive said pin when the body of the guide needle is situated respectively in said forward working position and in said retracted safety position (Fig 9; col 5, lns 12-col 8, lns 14);safety catheter that comprises guide means able to guide the axial sliding of said guide needle body inside catheter (20);safety catheter characterized in that said guide means comprise a longitudinal slot formed in the catheter body and ending in said front and rear seats to allow guided sliding of said pin in longitudinal slot (20); including a safety catheter comprising spring means disposed in catheter between abutment surface in front wall and said spring means being under compression, when guide needle body is in forward working position and being released when guide needle is in retracted safety position (100; col 5, lns 12-col 8, lns 14; Figs 13a, b); the spring being compressed so that upon release the spring biases the catheter body and the guide needle body in opposite directions so that the guide member and the guide needle body retract with respect to the catheter body to dispose the guide needle in the retracted safety position, the entire guide needle being protected by the catheter body (100; col 5, lns 12-col 8, lns 14; Figs 13a, b).

13. Claims 1-5, 8, 9, 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al (6786875). Barker et al discloses a safety catheter comprising: a catheter body (100) having an axial channel communicating with a sheath or cannula (130) for administration of fluids, a guide needle (165), insertable through the channel of the

catheter body, into the sheath to guide it during insertion into the patient's body, and a guide needle body supporting said guide needle insertable inside the catheter body and provided with at least one seat (Fig 4-5, 172) for coupling with medical instruments, characterized in that said body of the guide needle is mounted slidably inside the catheter body to be able to slide from a forward working position wherein the guide needle protrudes forward from the catheter body (Figs 6-7) to a retracted safety position wherein the entire guide needle is protected inside the catheter body (Figs 6-7), there being provided locking means (142), disposed in said body of the guide needle, cooperating with complementary locking or stop means (122, 150) disposed in the catheter body, to lock the body of the guide needle respectively in said forward working position and in said retracted safety position, and the needle moving into the retracted safety position in a continuous movement under a pushing force of a spring means (160); including a safety catheter in that said locking means comprises a pin and said complementary locking means provided in the catheter comprises two seats disposed at the front and at the rear to receive said pin when the body of the guide needle is situated respectively in said forward working position and in said retracted safety position (Figs 6-7; col 6, lns 53-col 8, lns 38); including said pin mounted on an elastic element connected to the guide needle body so as to be able to be squeezed manually by the operator, causing elastic yielding of said elastic element to disengage itself from said front seat of catheter when the guide needle is in said forward working position (143, 142; Figs 6-7, Figs 6-7; col 6, lns 53-col 8, lns 38);a safety catheter in that said elastic element supporting the pin consists of an elastic tongue defined by a U-shaped

cut in said guide needle body and disposed in a longitudinal seat formed in the guide needle body so as to be able to bend in said longitudinal seat (152; col 8, lns 19-58);safety catheter that comprises guide means able to guide the axial sliding of said guide needle body inside catheter (Figs 6-7; col 6, lns 53-col 8, lns 38);including a complementary locking or stop means disposed in catheter with an elastic tongue in the rear of catheter where it's defined by U-shaped cut formed in body having a free end protruding inward to abut against surface formed in front of body of guide needle, where guide needle is in its retracted safety position (Figs 6-7; col 6, lns 53-col 8, lns 38);including a safety catheter comprising spring means disposed in catheter between abutment surface in front wall and said spring means being under compression, when guide needle body is in forward working position and being released when guide needle is in retracted safety position (Figs 6-7; col 6, lns 53-col 8, lns 38); the spring being compressed so that upon release the spring biases the catheter body and the guide needle body in opposite directions so that the guide member and the guide needle body retract with respect to the catheter body to dispose the guide needle in the retracted safety position, the entire guide needle being protected by the catheter body (Figs 6-7; col 6, lns 53-col 8, lns 38).

14. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Amico (5279579). D'Amico discloses a safety catheter comprising: a catheter body (100, Fig 20-23) having an axial channel communicating with a sheath or cannula (102; Figs 20-23) for administration of fluids, a guide needle (Figs 20-23), insertable through

the channel of the catheter body, into the sheath to guide it during insertion into the patient's body, and a guide needle body supporting said guide needle insertable inside the catheter body and provided with at least one seat (Figs 20-23) for coupling with medical instruments, characterized in that said body of the guide needle is mounted slidably inside the catheter body to be able to slide from a forward working position wherein the guide needle protrudes forward from the catheter body (Figs 20) to a retracted safety position wherein the entire guide needle is protected inside the catheter body (Figs 21), there being provided locking means (106), disposed in said body of the guide needle, cooperating with complementary locking or stop means (113, 111) disposed in the catheter body, to lock the body of the guide needle respectively in said forward working position and in said retracted safety position, and the needle moving into the retracted safety position in a continuous movement under a pushing force of a spring means (109); including a safety catheter in that said locking means comprises a pin and said complementary locking means provided in the catheter comprises two seats disposed at the front and at the rear to receive said pin when the body of the guide needle is situated respectively in said forward working position and in said retracted safety position (Figs 20-23); including said pin mounted on an elastic element connected to the guide needle body so as to be able to be squeezed manually by the operator, causing elastic yielding of said elastic element to disengage itself from said front seat of catheter when the guide needle is in said forward working position (106; wherein the Examiner notes the pin (106) is the same as pin (76) – see Figs 15-19; col 6, lns 36-39);a safety catheter in that said elastic element supporting the pin consists of

an elastic tongue defined by a U-shaped cut in said guide needle body and disposed in a longitudinal seat formed in the guide needle body so as to be able to bend in said longitudinal seat (Figs 20-23; 108, 76);safety catheter that comprises guide means able to guide the axial sliding of said guide needle body inside catheter (104); safety catheter characterized in that said guide means comprise a longitudinal slot formed in the catheter body and ending in said front and rear seats to allow guided sliding of said pin in longitudinal slot(104);safety catheter where said front and rear seats are circular in shape with a slightly larger diameter than the width of said longitudinal slot and said pin comprises a cylindrical base part having a larger diameter than upper cylindrical part, diameter of said base of pin being smaller than diameter of said front and rear seats and greater than the width of slot and diameter of top part of pin being smaller than width of longitudinal slot (Figs 20-21 and 13-18);including a complementary locking or stop means disposed in catheter with an elastic tongue in the rear of catheter where it's defined by U-shaped cut formed in body having a free end protruding inward to abut against surface formed in front of body of guide needle, where guide needle is in its retracted safety position(Figs 20-23; col 6, lns 36-col 7, lns14);including a safety catheter comprising spring means disposed in catheter between abutment surface in front wall and said spring means being under compression, when guide needle body is in forward working position and being released when guide needle is in retracted safety position (109; Figs 20-23; 60', Figs 16-17); including a spring means comprising spiral spring around a cylindrical tang in front of guide needle body so as to define said abutment surface of guide needle body and having a smaller diameter than the guide

needle body (109; Figs 20-23; 60', Figs 16-17); wherein, the spring means comprises a spiral spring disposed around a cylindrical tang disposed in front of said guide needle body (109; Figs 20-23; 60', Figs 16-17) so as to define said abutment surface of the guide needle body and having a smaller diameter than the guide needle body (109; Figs 20-23; 60', Figs 16-17), the spring being compressed so that upon release the spring biases the catheter body and the guide needle body in opposite directions so that the guide member and the guide needle body retract with respect to the catheter body to dispose the guide needle in the retracted safety position, the entire guide needle being protected by the catheter body (109; Figs 20-23; 60', Figs 16-17).

Response to Arguments

15. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER